

DETAILED ACTION

Applicants' Amendment, filed 1/11/08, has been entered. Claims 31-43, 46-59 and 64 are pending; claims 44, 45, 61 and 63 are cancelled; claims 31-42 and 46-59 are withdrawn; claims 43 and 64 are under current examination.

This rejection is **non-final**.

Election/Restrictions

Claims 31-42 and 46-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/4/05.

Applicant's election without traverse of Group XII (claims 43-45, 60 and 61) in the reply filed on 8/4/05 is acknowledged.

Information Disclosure Statement

Applicants' IDS, filed 1/11/08, has been considered.

Claim Rejections - 35 USC § 112

The prior rejection of claims 43-45, 61, 63 and 64 for enablement, is withdrawn in view of Applicants' amendment to claim 43, which now recites "human" and the cancellation of claims 44, 45, 61 and 63.

Claim Rejections - 35 USC § 112

The prior rejection of claims 45, 61 and 64 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43 and 64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 98/17791 (Purchio *et al.*, published April 30, 1998).

The claims are directed to an isolated purified homogenous culture of viable human precursor cells isolated from periosteum, bone marrow, or synovial membrane, that have entered a post-natal skeletal differentiation pathway leading to skeletal or connective tissue, wherein the cells express a positive embryonic marker. Further embodiments are directed to the further characterization of the cells by the absence of expression of a marker selected from the group consisting of FGFR4, type II collagen, type IX collagen, type X collagen, type XI collagen and BMP-2.

Claim Interpretation. The claims are interpreted as follows: the source from which the cells are isolated (periosteum, bone marrow or synovial membrane) do not impart patentable weight to the resultant cells. Therefore, cells that are isolated,

purified homogenous cultures of viable, differentiated human precursor cells that are capable of differentiation into skeletal or connective tissue fulfills the limitations of the claims. The expression of CDMP-1, or lack of the markers recited in claim 64 would be inherent in these cells. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The '791 document teaches the isolation of human pre-chondrocyte cells from Wharton's jelly. In particular, the '791 document discusses the isolation of pre-chondrocytes, and the differentiation of these cells into cartilage tissue, as well as the establishment of banks of pre-chondrocytes (see p. 18, lines 29-33, for example). The '791 document teaches method to isolate the pre-chondrocytes (p. 19, #5.9) and the expansion of the cells. Accordingly, the '791 document anticipates or renders the claimed invention obvious because they teach isolated, purified homogenous cultures of human pre-chondrocytes that are capable of producing cells of connective tissue. These cells would inherently have the property of expression the markers required by the claims.

Claims 43 and 64 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over 5,919,702 (Purchio *et al.*, issued July 6, 1999).

The claim interpretation has been summarized above. Purchio discuss isolation of pre-chondrocytes from Wharton's jelly. Pre-chondrocytes are differentiated human precursor cells that produce cartilage (connective tissue). Purchio teach that isolated pre-chondrocytes give rise to chondrocytes that can be induced to form cartilage (col. 1, lines 10-15). Purchio teach methods of isolating pre-chondrocytes (col 10-11), and methods to purify these cells such that the cells

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can be expanded (col. 11, lines 50-59). Accordingly, Purchio anticipate or render the claimed invention obvious because they teach isolated, purified homogenous cultures of human pre-chondrocytes that are capable of producing cells of connective tissue. These cells would inherently have the property of expression the markers required by the claims.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632